I. Revisions to Parts 435, 440, and 447; Miscellaneous Comments

In addition to the provisions set forth in the new part 438 and the fair hearing provisions in part 431 discussed in section II. E. of this preamble, the proposed rule contained amendments to parts 435, 440, and 447 that we discuss below. These provisions included amendments to §§435.212 and 435.326 to reflect the new terminology adopted by the BBA. We also proposed a new §440.168 in part 440 to include a description of primary care case management services. Amendments to part 447 not already addressed above include a new §447.46(f) implementing the timely claims payment requirements in section 1932(f), and a new §447.60 regulating MCO cost-sharing, which was made permissible under BBA amendments to section 1916 of the Act. In this section, we discuss the comments we received on the above regulations. We received no comments on the revisions to §447.60. In this section, we also address miscellaneous comments that did not relate to a specific section of the proposed regulations.

1. Guaranteed Eligibility (Proposed §435.212)

Section 435.212 was revised in the proposed rule to implement section 1902(e)(2) of the Social Security Act. This change will permit State agencies, at their option, to provide for a minimum enrollment period of up to 6 months for individuals enrolled in a PCCM or any MCO. Previously, this option was only available to enrollees of Federally qualified HMOs.

Comment: One commenter expressed support for this provision.

Response: We thank the commenter for the support.

2. Definition of PCCM Services (Proposed §440.168)

Section 4702 of the BBA added PCCM services to the list of optional Medicaid services in section 1905(a) of the Act. The BBA also added section 1905(t) to the Act.

This subsection defines PCCM services, identifies who may provide them, and sets forth requirements for contracts between PCCMs and the State agency. This means that in addition to contracting with PCCMs under a section 1915(b) waiver program or section 1115 demonstration project, or under the new authority in section 1932(a)(1) to mandate managed care enrollment, States may add PCCMs as an optional State plan service. Regardless of the vehicle used, proposed §438.6(k) set forth the minimum contract requirements States must have with their primary care case managers.

Proposed §440.168(a), implementing section 1905(t)(1) of the Act, defined "primary care case management services" as case management related services that include locating, coordinating and monitoring health care services, and that are provided under a contract between the State and a primary care case manager. A PCCM was defined as including either (1) an individual physician (or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife), or (2) a group practice or entity that employs or arranges with physicians to furnish services. Proposed §440.168(b) provided that PCCM services may be offered as a voluntary option under the State plan, or on a mandatory basis under section 1932(a)(1) or under a section 1115 or section 1915(b) waiver.

Comment: One commenter disagreed with the language designating it a "State's Option" to qualify nurse practitioners as PCCM providers. The commenter believes nurse practitioners should be recognized as PCCM providers by the Medicaid program. It is critical that CMS ensure that Medicaid beneficiaries have the option to choose a nurse practitioner as their PCCM provider.

Response: The definition of a primary care case manager in §438.2 of this part mirrors the statutory language in section 1905(t)(2) of the Act. The statute is clear that

there are two categories of PCCMs. The first category is PCCMs that are physicians or physician groups, or that employ or arrange for the provision of physician services. The definition of a physician does not include a nurse practitioner. (See sections 1905(a)(5)(A) and 1861(r)(1) of the Act.) The second category is non-physicians who are included as PCCMs "at State option." The statute expressly provides for nurse practitioners to be PCCMs "at State option."

3. Timely Claims Payment by MCOs (Proposed §447.46)

Section 1932(f) of the Act specifies that contracts with MCOs under section 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for items and services covered under the contract must be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. Section 1902(a)(37)(A) of the Act requires that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for covered services provided by health care providers are paid within 30 days of receipt, and that 99 percent of the claims are paid within 90 days of receipt. These requirements were included in proposed §447.46. We received no comments on this section.

4. Miscellaneous Preamble Comments

a. Effective Date of the Final Rule

Comment: Numerous commenters offered suggestions for the effective date and timeframe for implementation of the final rule. The commenters urged CMS to provide an adequate opportunity for MCOs and States to come into compliance with the regulation following its effective date as implementation will require both States and MCOs to make substantial changes to contracts, waivers, and other State procedures. One commenter

recommended that the effective date be 180 days after the State's MCO contract renewal date following publication of the final rule. A few commenters recommended that States be given 2 years to come into compliance with the final rule. Several other commenters recommended that a full year be given for all contracts, regardless of their renewal date, to come into compliance with the final rule.

Response: We agree with the commenters that adequate time needs to be given for implementation of this final rule. Therefore, we have established that the final regulation will become effective 60 days post publication, and must be fully implemented by 1 year from the effective date of the regulation. This would allow new provisions to be implemented without forcing States to amend contracts in mid-term, although States would have the option to implement portions of the regulation in the interim period.

b. Violation of APA

Comment: A few commenters contended that the August 20, 2001 proposed rule did not comply with the Administrative Procedure Act (APA) as interpreted by the Supreme Court in Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29 (1983). Specifically, the commenters suggested that we did not comply with the requirement in that case that agencies supply reasoned analysis in support of a change in policy. The commenters also quoted the U.S. Court of Appeals for the District of Columbia's decision in National Black Media Coalition v. FCC, 775 F.2d 342, 356 n. 17 (D.C. Cir. 1985) for the proposition that "an agency may not repudiate precedent simply to conform with shifting political mood," and that "the agency must demonstrate that its new policy is consistent with the mandate with which the Congress has charged it." In citing these cases, these commenters were comparing the regulations in the August 20, 2001 proposed rule, to those in the January 19, 2001 final rule that never took effect. The

commenters believe that we were required in the proposed rule to explain any differences between the rules proposed in the August 2001 proposed rule and those published on January 19, 2001 and find support in "the rulemaking record" for any such differences.

Response: The cases cited by the commenters concern changes made to existing regulations. In those cases, regulations had been published and taken effect, and the agencies were making changes to existing regulations. In this case, as noted in the previous comment, the effective date of the January 19, 2001 final rule was delayed, and those regulations had never taken effect. Thus, there are no "existing regulations" in part 438 that this proposed rule would "change." Rather, the existing regulations governing Medicaid managed care are the regulations in part 434 which predate the earlier rulemaking that led to the January 19, 2001 final rule. We believe that the preamble to the proposed rule clearly articulates our reasons for proposing changes to these existing part 434 regulations. Most of the major changes in the proposed rule implement, or are based on, Medicaid managed care provisions in the Balanced Budget Act of 1997 (BBA), which was enacted after the existing part 434 regulations were promulgated. When we proposed changes in policy not directly based on BBA provisions, the preamble explains the basis for the policy choice made, including discussion of inadequacies in the part 434 regulations, when appropriate.

We note that, while not required to do so by the cases cited by the commenters, we did explain in the preamble our rationale for the departures in this proposed rule from the approach taken in the January 19, 2001 regulations. We indicated that in developing this proposed rule, we were "guided by several considerations" set forth in detail in the preamble. (See 66 Fed. Reg. 43616.) For example, we indicated that the proposed rule was designed to recognize that Medicaid is a "Federal-State partnership" under which

"States are assigned the responsibility of designing their State programs" and need the flexibility to "employ different approaches to achieving the same goal within their varying State marketplaces and health care delivery systems." We also noted "new advances and findings in health care, health quality assessment and improvement" that "unfold on an almost daily basis," and noted that regulations containing too rigid a structure are not able to adapt to these changes. The extent to which some aspects of the proposed rule differed from those in the January 19, 2001 rule is attributable to our reassessment, described above.

c. Applicability of BBA Provisions and Other Parts of this Final Rule to Waiver Programs

Section 4710(c) of the BBA specifies that the requirements in sections 4701 through 4710 do not affect the terms and conditions of any demonstration projects or waiver programs approved by the Secretary under the authority of sections 1115 or 1915(b) of the Act. We have consistently interpreted this to be a "grandfather" provision that applies only to waivers or demonstration projects that were in effect, or already approved, as of August 5, 1997, the date of enactment of the BBA. Thus, when the waiver or demonstration project expires, the grandfather provision in section 4710(c) no longer applies.

Under section 4710(c), the grandfather provision applies to the "terms and conditions" of a waiver. Any provisions of a State's section 1115 demonstration project or section 1915(b) waiver program that were specifically addressed in the State's waiver proposal, statutory waivers, special terms and conditions, operational protocol, or other official State policy or procedures approved by us, are considered to be the "terms and conditions" of the waiver. To the extent the terms and conditions of the State's approved

waiver program covered the same subject matter as any of the BBA requirements, that portion of the State's program would not have to comply with the BBA until the waiver expired. For example, if the State's waiver program included enrollment and disenrollment rules, the enrollment and disenrollment rules in section 1932 of the Act would not apply while the waiver was still in effect. For any part of the State's Medicaid managed care program that was not within the scope of the waiver, the BBA provisions applied immediately, with certain exceptions specified below, dealing with newly submitted or amended waivers.

As noted above, under our interpretation, the exemption from the BBA requirements applied to section 1915(b) waiver programs only until the date that the waiver authority that was approved or in effect as of August 5, 1997 expired. Because none of those waivers exceeded two years, all of them expired no later than 1999. After the waiver expired, the State was required to comply with all BBA requirements. Similarly, in the case of section 1115 demonstration projects, the "grandfather" provision in 4710(c) only applies until the demonstration expires, as established by the expiration date that appears in the waiver documents that were approved or in effect on August 5, 1997. However, section 1115(e) of the Act provides a State with a statutory right to extend any waiver previously approved under 1115(a), on the same "terms and conditions," unless the Secretary specifically disapproves the extension. This extension can be for up to three years. As long as the State applies for an extension under section 1115(e) while its demonstration project is still subject to the "grandfather" provision described above, the statutory requirement that the waiver continue under the "same terms and conditions" means that those waiver provisions cannot be subject to the BBA requirements until the extension expires. The Medicare, Medicaid, and State Child Health Insurance Program

Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000 (Pub. L. 106-554) added section 1115(f) of the Act, to provide for additional extensions of section 1115 health care reform demonstrations. Unlike section 1115(e), section 1115(f) does not require that the demonstration project be extended under the same terms and conditions, providing, instead, for the negotiation of new terms and conditions. Therefore, unless the Secretary uses his discretionary authority to waive the requirements, as explained below, the BBA requirements apply to all demonstration projects approved under section 1115 except during the "grandfather" period and any subsequent extension under section 1115(e)(2).

For newly submitted or amended section 1115 waivers, the Secretary of DHHS retains the discretionary authority to exempt the State from specific BBA managed care provisions. Generally, exemptions are granted to allow States some flexibility in operating their Medicaid programs, while promoting the proper and efficient administration of a State's plan. However, particularly for those BBA provisions related to increased beneficiary protections and quality assurance standards, we anticipate that we would not approve an exemption unless a State can demonstrate that the waiver program has beneficiary protections or quality standards that would equal or exceed the BBA requirements.

In addition, the Secretary may use his discretionary authority (to the extent permitted by the specific waiver provision) to waive other requirements in this rule which do not implement provisions of the BBA, such as the new rate setting requirements, requirements that apply to PIHPs and PAHPs, and requirements that were redesignated from part 434 or other parts of 42 CFR.

Comment: Several commenters questioned the applicability of these rules to

waiver programs. One commenter wanted CMS to confirm the belief that the proposed rule does not apply to States with current section 1115 demonstrations, while another wanted CMS to specify in the text of final rule that these regulations do not apply to waiver programs under section 1115 or 1915(b), to be consistent with section 4710(c) of the BBA. Another commenter supported CMS' decision to apply the final rule to both new and renewed section 1115 and 1915(b) waivers.

Response: As stated in the proposed rule and reiterated above, section 4710(c) of the BBA is time-limited, has expired for all section 1915(b) waiver programs, and only applies to section 1115 health care reform demonstrations during the period of approval that was in effect as of August 5, 1997 and any 3-year extension periods granted under the authority in section 1115(e)(2) of the Act. We disagree with the suggestion that the provisions of this part should never apply to programs conducted under these waivers.

Comment: One commenter asked that CMS grant States flexibility in applying these rules through 1915(b) waivers, but another commenter opposed the decision to consider granting any new waivers of these requirements.

Response: As indicated above, waiver authorities in section 1915(b) and 1115 remain in effect. If a State requests a waiver in order to implement an alternative approach for its Medicaid program that requires a waiver of provisions contained in this rule, while maintaining necessary beneficiary protections and meeting the specific requirements of the waiver authority requested, we may grant the waiver. We believe granting these waivers reflects the intent of the Congress which did not modify or limit the authority in either of these waiver provisions.

Comment: One commenter asked to what extent the provisions in this rule apply to section 1915(c) waiver programs.

Response: To the extent any provisions of these rules are relevant to the contract requirement, payment mechanisms, enrollment, or any other aspect of a program operating under a section 1915(c) waiver authority, the requirements apply. While we do not believe that most current 1915(c) programs would be subject to any of these requirements, any program operating under a combined 1915(b) and (c) authority which includes such things as an enrollment lock-in period, a capitated reimbursement methodology, or a provider that qualifies as a PAHP, would have to comply with the provision of this final rule as applicable.

See section II.E. of this preamble for further discussion regarding the applicability of the BBA requirements to States with waivers.

d. Education of MCOs, PIHPs, PAHPs, and PCCMs about special health care needs.

Comment: Many commenters believe that there should be language stating that the "State agency must have in effect procedures for educating MCOs, PIHPs, PAHPs, PCCMs, and any subcontracting providers about the clinical and other needs of enrollees with special health care needs." The commenters stated that this is an essential way for the State to ensure that health plans, that have not traditionally served Medicaid enrollees or enrollees with special health care needs, understand those needs. Another commenter stated that managed care must be sensitized to the needs of special needs beneficiaries, for whom disruptions in service and impediments to access can be serious.

Response: While we understand the need for awareness of special health care needs, we want to give States the flexibility to decide at what level this should happen. Many States may not have the capability or feel that it is appropriate for the State to provide education to MCOs, PIHPs, PAHPs, PCCMs, and providers on what is often a

clinical issue. Public health departments and local medical societies are often doing this type of work in the State.

e. Miscellaneous comments

Comment: Numerous commenters applauded CMS for amending the Medicaid managed care regulations with the proposed rule published on August 20, 2001. Commenters appreciated that the proposed regulation removed much of the prescriptiveness of the requirements and acknowledged the expertise and work that continues at the State level. Most commenters were pleased to see a renewed emphasis on State flexibility. The proposed rule changed the focus from detailing how States and MCOs should operate to laying out the basic requirements for Medicaid managed care and allowing States the authority to implement them in a manner appropriate for each State. Further, commenters stated that the new rule simplified many of the provisions and eliminated redundancy so that requirements are stated only once. Commenters believe that the simplification of the regulation and removal of duplicative and redundant provisions will help States to accurately interpret, follow, and enforce this regulation.

Other commenters stated that the proposed rule will permit innovation and support program growth under standards that respond to the needs of the full spectrum of enrollees and implementation of the January 2001 rule would have seriously undermined the availability of the benefits of MCOs to Medicaid beneficiaries. Another commenter believes that removal of much of the highly detailed language contained in the January 2001 rule will enhance the ability of both the Federal and State governments to exercise responsibilities as purchasers and regulators effectively. Further, States have proven their ability to innovate in the quality arena and will continue to strive towards providing the highest quality care to Medicaid beneficiaries. Several other commenters noted that the

proposed rule is a significant improvement over the rules published in January 2001, many provisions of which would have significantly raised health plan compliance costs without meaningfully improving patient care. One commenter urged immediate implementation of the proposed rule.

Response: We thank the commenters for their support. We will continue to work with States during the implementation period of the final rule.

Comment: Numerous commenters expressed their dissatisfaction with the proposed rule published on August 20, 2001. These commenters strongly support the immediate implementation of the January 19, 2001 final rule. Most of these commenters stated that the January rule reflected a true balance between providing States additional flexibility and providing Medicaid beneficiaries, including those with disabilities, the protections they need to ensure that Medicaid managed care meets their needs; that the revised proposed rule and the accompanying delays in implementation demonstrate that the Administration is more attuned to the desires of the States and managed care industry than to the needs of the people who are supposed to benefit from the Medicaid program; that the proposed rule pays too little attention to the special needs of children and adults with mental retardation and other disabilities. These commenters believe that the January rules establish important new protections for beneficiaries with respect to access to care, grievance and appeal procedures, and mandatory enrollment requirements.

Other commenters stated that more specific requirements are warranted related to transitioning children into and out of managed care, and the identification, screening and assessment of children with special health care needs. Some commenters urged CMS to strengthen the proposed rule to ensure safeguards for children with special health care needs, consistent with the waiver criteria for children with special health care needs.

These commenters also called upon CMS to incorporate the recommendations of the Department's November 2000 Report to the Congress entitled "Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care" into the regulation.

Another commenter expressed concern that many provisions of the proposed rule do not provide adequate protections for consumers of mental health and substance abuse services enrolled in managed care plans through the Medicaid program. The commenter further suggested that the proposed rule unjustifiably undermines the consumer safeguards established in the January 2001 final rule. Another commenter specified that the proposed rule represents a profound failure to implement the statutory provisions of the BBA and does not provide even basic patient protections. These commenters urged CMS to reinstate many aspects of the January rule, which they believe better effectuate the BBA. Many other commenters believe that if the proposed rule is implemented it will be extremely harmful to Medicaid beneficiaries with special health care needs, including people living with HIV/AIDS.

Response: In development of the proposed and final rules we gave serious attention to all of the concerns raised to us. We believe the final rule reflects the path chosen by the Congress to strike an appropriate balance between State flexibility and beneficiary protections. We believe that this final rule reflects that balance and appropriately implements the beneficiary protections established by the BBA. We believe all commenters have expressed the same goal, namely: strong, viable, State Medicaid managed care programs that deliver high quality health care to Medicaid beneficiaries. We believe that the final rule will help States achieve this goal. The Congress drafted the statute in full recognition of the Medicaid program as a Federal-State partnership and we

share that recognition. States are assigned the responsibility of designing their State programs. We drafted this regulation to recognize the responsibilities of the States and the need to employ different approaches to achieving the same goal within their State marketplaces and health care delivery systems. We heard from some key stakeholders in Medicaid managed care, including States, provider organizations, and advocates for beneficiaries. Some of these stakeholders expressed serious concerns about the regulation, including changes made to the January 2001 final rule that had not been included in the September 1998 proposed rule. Other stakeholders strongly supported the January 2001 final rule and urged us to continue with implementation. We decided that the best approach was to make some modifications to the January 19, 2001 final rule and republish it as a proposed rule in order to give everyone the opportunity to comment on all of the provisions.

We believe we have created a set of requirements that appropriately balances the necessary protections for all beneficiaries enrolled in Medicaid managed care plans, including individuals with special health care needs, and States' flexibility to manage their managed care programs. We have not reduced the emphasis on requiring States to provide high quality care to beneficiaries, especially those with special needs. The rule requires States to identify managed care enrollees with special needs to make sure that they will receive appropriate access to quality care. States retain the flexibility to develop these mechanisms and define the special needs populations. This approach enables States to better target their Medicaid resources to those most in need. We believe this is a far more efficient approach than imposing regulatory burdens that may not have their intended effects.

Comment: One commenter expressed concern that the August 20, 2001 proposed

rule did not contain important regulatory language that was included in the 1998 proposed rule supportive of protections for the mentally ill in Medicaid managed care. The commenter pointed out that a number of its recommendations were not included and the commenter requests an explanation for these negative decisions.

Response: The regulation, as now written, is intended to address the needs of, and protections for, all Medicaid beneficiaries in managed care, including persons with disabilities and those who suffer from mental illness. The regulation is written in a manner to establish a general framework for States to use when developing managed care programs to serve all of its enrolled populations. Therefore, we do not believe it is necessary to list specific medical conditions within the regulation text. As far as comments received on the September 28, 1998 proposed rule, responses to all of the comments and rationale for changes can be found in the January 19, 2001 final rule preamble.

Comment: A few commenters, while supportive of the fact that CMS delayed implementation of the January 2001 final rule and then made substantial revisions in the August proposed rule, were still concerned that the proposed rule will increase the cost and administrative burden associated with Medicaid managed care. The commenters believe that health plans serving members other than Medicaid beneficiaries will be placed at a disadvantage. The commenters also urged CMS to take steps to encourage commercial plans and providers to participate in Medicaid managed care programs and to regulate the program in a manner that allows States to continue moving forward with managed care. Another commenter expressed concern regarding the overall impact on access, quality of care and cost effectiveness of applying the regulations to specialty mental health programs. And to the extent CMS does not provide more flexibility to States in these regulations, it should seriously consider providing reasonable flexibility to States

in the section 1915(b) waiver process. Another commenter stated that the speed with which these rules have been rewritten has lead to a proposed rule that shows a lack of clarity and careful consideration. The regulatory process did not provide for adequate participation by the States with the knowledge and experience to help draft effective and efficient rules for managed care. The commenter urged CMS to involve State representatives in a final rewrite of the rule. In addition, when considering the imposition of every new administrative requirement, CMS needs to be cognizant that each of those requirements costs the States' increasingly limited resources that could better be focused on provision of care. Further, every new requirement on MCOs and providers can affect their continued participation in managed care. Another commenter advised CMS to keep in mind that as regulations are designed with particular focus on enrollee protections, it is critical to keep in mind that overly prescriptive requirements that shift potentially unnecessary administrative costs and burdens to plans and providers may result in the unintended consequence of provider and/or plan withdrawal from the Medicaid program. This could then lead to impeded access to quality care for vulnerable populations.

Response: The regulation was developed to provide States with an appropriate level of flexibility that we believe to be consistent with necessary beneficiary protections. State flexibility had to be balanced against the statutory requirements of the BBA. Further, the regulation has been designed to provide a framework that allows CMS and States to continue to incorporate further advances for oversight of managed care, particularly as they pertain to beneficiary protection and quality of care. We recognize that States are unique and have different needs for their enrolled populations. This final rule was designed to promote State flexibility as much as possible so that States can implement managed care programs that meet the needs of their beneficiaries. With

respect to MCO and provider participation, we further believe that the new rate-setting provisions will allow States to set rates that more appropriately reflect the costs of health services for the variety of Medicaid populations served, especially those with special health care needs.

Comment: One commenter stated that changes should be made to the proposed rule to ensure that providers are compensated in a timely manner, so they can continue to provide needed services to low-income patients.

Response: Section 1932(f) of the Act specifies that contracts under 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for services covered under the contract be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. These procedures require that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for services covered under the contract and provided by health care providers are paid within 30 days of receipt, and that 99 percent of the claims are paid within 90 days of receipt. These requirements are included in §447.46. We do not believe that additional changes need to be made.

Comment: One commenter noted that the proposed rule does not take into consideration the frontier nature of some States. Many of the provisions would be difficult to meet even for the non-Medicaid population.

Response: We believe this final rule affords States the flexibility to implement these requirements for Medicaid managed care in all areas of their State. Further, the final rule provides for an exception to the choice requirements (§438.52) for residents in rural areas.

Comment: One commenter stated that these rules continue to require monitoring and oversight on issues that would result in higher requirements for Medicaid enrollees than for fee-for-service Medicaid or the general population. The commenter noted that it remains a distressing tendency to enforce things for managed care that are not enforced for the fee-for-service population.

Response: While CMS agrees that beneficiary protections are also important for beneficiaries receiving care under fee-for-service arrangements, this rulemaking implements Chapter 1 of Subtitle H of the BBA, titled "Managed Care." These statutory provisions do not apply to fee-for-service Medicaid, and cannot be extended to fee-for-service arrangements in this final rule. However, States do have the flexibility to develop beneficiary protections similar to those presented in this regulation for those still receiving care through fee-for-service. States may establish similar standards that can be monitored on the same scale as those standards established for Medicaid managed care. We agree that it is important to recognize that beneficiaries are afforded additional assistance in managed care than may be afforded in fee-for-service.

Comment: One commenter noted that when establishing protections for Medicaid managed care beneficiaries, CMS should recognize that oral health is an inseparable part of an individual's overall health and the formation of an effective Medicaid dental delivery system is just as important as the creation of an adequate Medicaid medical delivery system. The commenter stated that all dental patients, whether they are in private plans, Medicaid fee-for-service or any Medicaid managed care arrangement, deserve equal access to health services and equal protections under the law.

Response: We recognize the importance of oral health and the importance of serving the dental needs of the Medicaid population. The final rule is designed to address

access issues related to all Medicaid managed care services. For example, an MCO or PAHP that delivers dental services to Medicaid beneficiaries must comply with the access requirements in this regulation. The MCO or PAHP must ensure that it offers an appropriate range of services and that it maintains a network of providers that is sufficient to meet the needs of enrollees. Further, each State must ensure that all of the covered services are accessible for all beneficiaries enrolled. We are also optimistic that managed care will facilitate increased utilization in the area of dental services.

Comment: One commenter expressed concern regarding some of the regulatory provisions, as they may pose or have a different effect in the territories, particularly since Medicaid funds are capped.

Response: We recognize the commenter's concern, however territories are required to meet all Medicaid requirements except for provisions specified in Federal law and regulation.

Comment: Several commenters stated that none of the Medicaid managed care rules has included any discussion of the need for State Medicaid programs to develop incentives for physicians to participate in Medicaid managed care plans. The commenters specified that lack of sufficient physician participation may pose a significant barrier to high quality care for Medicaid beneficiaries. Development of incentives for physician participation should be a central issue for Federal and State governments as they design, implement and evaluate managed care programs. One commenter recommended that State agencies be required to consult with State medical societies early on in the process of designing Medicaid managed care programs and continue to seek input from the physician community throughout implementation. The commenter cited a recent report from the American Academy of Pediatrics that concluded "in order to ensure that expanding

insurance coverage for children translates into viable access to care, States must provide incentives for pediatricians to extend their resources to serve new Medicaid and SCHIP enrollees."

Response: We realize that physician consultation is an important factor in the development of Medicaid managed care initiatives and encourage stakeholder input at all stages of managed care development. However, we are not specifically requiring stakeholder involvement since States, based on the uniqueness of their Medicaid managed care programs, are in the best position to determine how this involvement should be structured. Each State is required to have a Medical Care Advisory Committee (MCAC) established for the purpose of advising the Medicaid agency about health and medical services. This committee, by regulatory definition, is required to include physicians. We encourage States to continue to use the MCAC as a mechanism for obtaining input on managed care issues. Likewise, under §438.202, we require public consultation in development of the State's quality strategy.

Comment: One commenter disagreed with the deletion of the requirement that no more than 75 percent of enrollees in risk contracts be eligible for Medicare or Medicaid.

Response: This change was made by the Congress in the BBA, and we thus had no discretion in this rulemaking to retain it. We note that this requirement was previously used as a rough "proxy" to ensure quality services by requiring that an MCO attract commercial consumers. This "proxy" has been replaced in the BBA with more direct quality requirements implemented in this final rule.

III. Summary of Changes to the Proposed Rule

For reasons discussed above in the preamble, we have made the following changes to the proposed rule:

Part 431 – State Organization and General Administration

Section 431.200

We have added language to include PAHP actions to suspend, terminate, or reduce services such as those that would result in access to the State fair hearing.

Section 431.220

We have included a new paragraph (a)(6) requiring that any PAHP enrollee who has an action must be granted the opportunity for a State fair hearing.

Section 431.244

We have added language in paragraph (f)(1)(i) to specify that the 90-day timeframe for resolution of the State fair hearing begins the date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing. In paragraph (f)(1)(ii) we clarify the regulation text to State that if permitted by the State, the date the enrollee filed for direct access to a State fair hearing.

In paragraphs (f)(2) and (f)(3) we have changed the limit for appeals of a denial of service by an MCO or PIHP 72 hours to three working days.

Part 438 – Managed Care Provisions

Subpart A – General Provisions

Section 438.1

In paragraph (b), we have included PIHPs in the scope of contracted entities provided in part 438.

Section 438.2

We moved the definition of "health care professional" from §438.102 to §438.2, as it applies to all of part 438.

We have clarified the definition of "health insuring organization" to reflect

language in section 1932(a)(3) of the act.

Section 438.6

In paragraph (c)(3)(ii), we have added language to clarify that we are referring to data factors such as medical trend inflation, incomplete data, and MCO, PIHP, or PAHP administration.

In paragraph (c)(4)(ii), we have added language to clarify that payment rates are based only upon services covered under the State plan, or costs directly related to providing these services (such as, MCO, PIHP, or PAHP administration.)

We removed proposed §438.6(c)(5)(ii) that referred to limitations on payment for risk corridors and incentive arrangements in proposed §438.814. We added new paragraph c)(5)(ii), which contains revised limitations on payment for risk corridors.

We added a new paragraph c)(5)(iii) that contains the payment limitations for incentive arrangements that were originally in proposed §438.814.

We have redesignated proposed paragraph (c)(5)(iii) as (c)(5)(iv).

We have removed proposed paragraph (c)(5)(iii)(C), which required that for all incentive arrangements, the contract must provide that the arrangement is designed to include withholds or other payment penalties if the contractor does not perform the specified activities or does not meet the specified targets.

We have included a new paragraph (c)(5)(v) to require that if a State makes payments to providers for graduate medical education costs under an approved State plan, the State must adjust the capitation rates to account for the aggregate amount of the graduate medical education payments to be made on behalf of enrollees covered under the contract.

We have included a new paragraph (i)(2) specifying that all PAHP contracts must also provide compliance with the advance directive requirements if the PAHP includes, in

its network, any of those providers listed under requirements on advance directives in §489.102(a).

Section 438.8

We have made revisions in paragraph (b)(1) to specify that PAHPs must meet the contract requirements of §438.6, except for those that pertain to HIOs and the requirements for advance directives unless the PAHP includes any of the providers listed in §489.102.

We have revised paragraph (b)(6) to require PAHPs to meet all designated portions of subpart D (Quality Assessment and Performance Improvement).

We have added a new paragraph (b)(7) to specify that PAHP enrollees have the right to a State fair hearing under subpart E of part 431 (State Organization and General Administration).

Section 438.10

We have added paragraph (b)(2) requiring that the State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care plan. We also added paragraph (b)(3) requiring each MCO and PIHP to have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

We have revised paragraph (c)(2) to require that the State must make available written information in each prevalent non-English language.

In paragraph (f) we rephrased the introductory language to require that information be furnished to MCO, PIHP, PAHP, and PCCM enrollees. In paragraph (f)(1) we have added language to clarify that for those States that choose to restrict disenrollment for periods of 90 days or more, notice of the enrollees disenrollment rights must be sent no less than 60 days before the start of each enrollment period. In paragraphs (f)(2) and (3)

we now include references to paragraphs (g) and (h) of this section to specify the information certain enrollees have a right to request and obtain at least once a year.

We have included, in paragraph (f)(4) that the State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must give each enrollee written notice of any change that is deemed significant in the specified information in paragraphs (f)(6) of this section and paragraphs (g) and (h) of this section, if applicable.

In paragraph (f)(6) we have clarified that the information in this section must be provided by the State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM. We have revised paragraph (f)(6)(i) to clarify that information on the names, locations, telephone numbers of, and non-English languages spoken by current contracting providers in the enrollees service area, including identification of providers that are not accepting new patients be provided to all enrollees. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists and hospitals. Further, in paragraph (f)(6)(iv) we add that for PAHP enrollees, the information specified in §438.10(h) must be provided.

We have revised paragraph (g)(3) to provide that detailed information of physician incentive plans is available upon request.

We have added a new paragraph (h) that requires specific information that must be provided for PAHP enrollees. The State, its contracted representative, or the PAHP must provide information to their enrollees on the right to a State fair hearing, including the right to a hearing, the method for obtaining a hearing, and the rules that govern representation. In paragraph (h)(2), we have specified that information must be provided on advance directives, as set forth in §438.6(i)(2) and in paragraph (h)(3) that, upon request, information must be provided on physician incentive plans as set forth in §438.6(h). We

have redesignated the previous paragraph (h) as paragraph (i) in the final rule.

We have clarified in paragraph (i)(2)(i) the timeframes for when information must be furnished to all enrollees of a State plan program under §438.50. For these enrollees, the timeframe is annually and upon request and for potential enrollees within the timeframe specified in §438.10(e)(1). In paragraph (i)(3), we have clarified that the information provided is only for each contracting MCO or PCCM in the potential enrollee and enrollee's service area. Finally, in paragraph (i)(3)(v), we have removed reference to disenrollment rates as defined by the States as information that must be included.

Subpart B – State Responsibilities

Section 438.60

We have included language allowing for payment exceptions when the State has adjusted the capitation rates paid under the contract, in accordance with §438.6(c)(5)(v), to make payments for graduate medical education.

Subpart C – Enrollee Rights and Protections

Section 438.100

We have moved paragraph (b)(3)(iii) regarding requests for medical records to new paragraph (b)(2)(vi). We have revised paragraph (b)(3) to specify that an enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§438.206 through 438.210. We have removed paragraph (b)(3)(ii), regarding the right to obtain a second opinion.

Section 438.102

We have moved the definition of health care professional to §438.2.

Section 438.104

We have revised paragraph (b)(1)(iv) to clarify that the requirement regarding the sale of other insurance applies to "private" insurance.

In paragraphs (b)(2) and (c) we have corrected cross-references to paragraphs (e) and (f) of §438.10.

Section 438.114

In paragraph (a) we have removed references to §422.113(b) and (c) and included the full text of definitions of emergency medical condition, emergency services and post-stabilization care services. In paragraph (d)(1)(ii) we have revised language to specify that entities may not refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, or applicable State entity of the enrollee's screening and treatment within 10 days of presentation for emergency services.

Subpart D – Quality Assessment and Performance Improvement

In subpart D, §§438.200, 438.206, 438.207, 438.208, 438.210, 438.214, 438.224, 438.230, and 438.236 have been amended by adding PAHPs to allow this network to have the same services.

Section 438.202

In paragraph (b) we replaced the words "provide for" with "obtain" and the words "including making" to "and make." In paragraph (c) we replaced the word "compliance" with the words "The MCOs, PIHPs, and PAHPs comply."

Section 438.204

In paragraph (b)(1) we have removed the word "including" and clarified that procedures must assess the quality and appropriateness of care and services furnished to Medicaid enrollees under the MCO and PIHP contracts, and to all individuals with special

health care needs. In paragraph (b)(3), we have clarified that the procedures must regularly monitor and evaluate the MCO and PIHP compliance with the standards. In paragraph (c) we have added, "For MCOs and PIHPs, any national" before "performance" and "that may be" before "identified." In paragraph (e) we have added the phrase "For MCOs," before "appropriate."

Section 438.206

In paragraph (a) we reversed the words "services" and "covered," and added the words "under the State plan" after "covered."

In paragraph (b)(1)(ii) we revised the second clause to read "taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP."

In paragraph (c)(1)(i) we added the word "the" between the words "of" and "need."

In paragraph (c)(1)(iv) we added at the end, the words "by providers."

In paragraph (c)(1)(v), we added the word "providers" after the word "Monitor" and replaced "continuously" with "regularly" to clarify that each MCO, PIHP, and PAHP must monitor regularly to determine compliance.

Section 438.207

In paragraph (a), we added the words "and providers supporting documentation that demonstrates" after the word "State."

In paragraph (b), we changed the title from "Nature of assurances" to "Nature of supporting documentation" and removed the words "acceptable to CMS."

In paragraph (c), we removed the words "and specifically" and replaced them with "but no less frequently than."

In paragraph (d) we replaced the word “submission” to “certification” in the title.

Section 438.208

Section 438.208 is revised. We have made significant changes to the organization of this section.

Section 438.210

In paragraph (a), we have reorganized and revised language for clarity.

Section 438.214

In paragraph (b) we have added a requirement that each State must establish a uniform credentialing and recredentialing policy that each MCO, PIHP, and PAHP must follow.

Section 438.240

In paragraph (a)(2) we have removed “standardized quality measures” and replaced it with “performance measures.” We have revised paragraph (b)(1) to require that performance improvement projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and non-clinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction. We redesignated paragraph (b)(2) as (b)(3) and we redesignated paragraph (b)(3) as (b)(4). We added a new paragraph (b)(2) to specify that each MCO and PIHP must submit performance measurement data, as described in paragraph (c) of this section.

In paragraphs (c) and (d)(2) we have clarified that each MCO and PIHP must annually measure and report to the State its performance (including requirements under §438.204(c) and §438.240(a)(2)), submit to the State data to enable the State to calculate measures, or perform a combination of the above activities.

Section 438.242

In paragraph (a) we have added "and appeals" after "grievances" to clarify that a health information system must provide information on appeals.

Subpart E—[Reserved]

Subpart F – Grievance System

Section 438.400

We have removed "or any of its providers" from the definition of "action." We have clarified the definition of "action," to include unreasonable delays in services or appeals not acted upon within the necessary timeframes provided in §438.408(b).

Section 438.402

In paragraph (b)(1)(ii) we clarified that a provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

Section 438.404

In paragraph (c)(6) we have corrected the cross-reference to §438.210(d) – timeframes for expedited service authorizations.

Section 438.406

We have revised paragraph (a)(1) to clarify that giving enrollees any reasonable assistance in completing forms and taking other procedural steps is not limited to providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

In paragraph (a)(3)(ii) we have clarified that the individuals who make decisions on grievances and appeals are individuals who are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's

condition or disease.

Section 438.408

In paragraph (d)(2)(ii) we have added language clarifying that the MCO or PIHP must also make reasonable efforts to provide oral notice.

Section 438.410

In paragraph (c)(2) we have added language clarifying the MCO or PIHP must make reasonable efforts to give the enrollee prompt oral notice of the denial.

Section 438.420

In paragraph (b)(4) we have included the word, "original" to describe the type of authorization.

In paragraph (c), we have added language to clarify the duration of continued or reinstated benefits. If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of the following occurs:

? The enrollee withdraws the appeal.

? Ten days have passed after the MCO or PIHP resolves the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

We have added a new paragraph (c)(4) to specify that benefits must be continued until the time period or service limits of a previously authorized service has been met.

Subpart G—[Reserved]

Subpart H – Certifications and Program Integrity

Section 438.600

We have added sections "1903(m)" and "1932(d)(1)" to the statutory basis to

establish conditions for payments to the State with respect to contracts with MCOs and to incorporate the BBA provisions prohibiting affiliations with individuals debarred by Federal agencies.

Sections 438.604 and 438.606

We deleted the requirement for "substantial compliance" with the terms of the contract and for submitting certifications for "substantial compliance" respectively in order to prevent unnecessary lawsuits against MCOs and States. In addition, the statute and regulations already require States to monitor compliance with contracts executed under this rule.

Section 438.610

We added a new section to incorporate language from section 1932(d)(1) of the Act to the regulation to implement the BBA provisions prohibiting affiliations with individuals debarred by Federal agencies. This self-implementing provision has not been published previously, but was added in the final rule to include all of the relevant protections against fraud and abuse in one section.

We added application to PCCMs and to PAHPs to this section. (The BBA provided that section 1932(d)(1) of the Act be applied to MCEs; therefore we included application to PCCMs. We applied this section to PAHPs under the authority of section 1902(a)(4) of the Act.

Subpart I – Sanctions

Section 438.724

We have clarified that the notice that must be given to the CMS Regional Office whenever a State imposes or lifts a sanction is only applicable to those sanctions under §438.700.

Section 438.726

We have added a new paragraph (b) which states that a contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as payment for those enrollees is denied by CMS.

Section 438.730

We have reorganized this section so that it conforms to removed §434.67.

Subpart J – Conditions for Federal Financial Participation

Section 438.802

We have removed the requirement for substantial compliance with physician incentive plans, the MCO's contract, and the provisions of part 438 as a condition for FFP.

Section 438.806

We have made technical revisions to correct erroneous cross-references in paragraph (a)(1). We now correctly refer back to paragraphs (b)(2) through (b)(5) of §438.6.

Section 438.814

We have revised and moved the provisions of this section to paragraphs (c)(5)(ii) and (c)(5)(iii) of §438.6.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the

following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA. For purposes of this requirement, we incorporated pertinent managed care data from the 2000 Medicaid enrollment report. As of June, 2000, there were 339 managed care organizations (MCOs) (this includes three HIOs that must adhere to the MCO requirements of this regulation), 37 primary care case management (PCCM) systems, 376 managed care entities (MCOs and PCCMs combined), 123 mental health and substance abuse prepaid health plans (PIHPs) and 34 dental, primary care and transportation prepaid health plans (PAHP), all of which have previously been regulated as PHPs. There were a total of 25,821,196 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in forty-eight States and the District of Columbia (Wyoming and Alaska do not currently enroll beneficiaries in any type of managed care).

A. Section 438.6 Contract requirements

Section 438.6(c) Payments Under Risk Contracts

1. Requirement

Section 438.6(c) modifies the rules governing payments to MCOs, PIHPs, and

PAHPs by doing the following: (1) eliminating the upper payment limit (UPL) requirement; (2) requiring actuarial certification of capitation rates; (3) specifying data elements that must be included in the methodology used to set capitation rates; (4) requiring States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates; (5) requiring States to provide explanations of risk sharing or incentive methodologies; and (6) imposing special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

2. Burden

It is difficult to quantify the burden on States of providing information to support the actuarial soundness of the capitation rates for their risk-based, managed care contracts, because the rate setting methodologies and data sources vary widely from State to State. Under the UPL requirements, States were required to provide the capitation rates and any requested supporting documentation for all rate cells used which may vary from 5 to 10 cells on one end to 60 or more on another. In addition, States needed to generate data to meet the UPL requirement using historical fee-for-service (FFS) data trended forward to the contract year. This would be a relatively simple process for a State initiating its managed care program, where it can rely on a very recent full year of FFS data for this purpose. However, almost all States have been operating risk-based managed care programs for at least 5 to 10 years and must make numerous adjustments to that data so that it can be used for this purpose. We estimate the average burden on States to comply with the current rate setting and UPL rules to be 16 hours per contract for documenting the capitation rates (setting out and explaining rate cells, risk sharing mechanisms, etc) and 40 hours per contract for generating a UPL for comparison purposes. This results in a total

burden of 56 hours per contract for 496 risk contracts, resulting in a total burden of 27,776 hours.

Under the new requirements for actuarial soundness, States will need to provide an actuarial certification and additional documentation not previously required, including: specific data elements used to set capitation rates; methodologies to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims; explanations of risk sharing or incentive methodologies; and documentation supporting special contract provisions. We estimate the burden to comply with these requirements to average approximately 32 hours per contract for the 496 risk contracts, resulting in a total burden of 15,872 hours. This amount is limited to the time required for the State to compile documentation the State and its actuaries would already have developed in determining the capitation rates and submitting this documentation, as required, to CMS. Since, under this new rule, States will no longer need to generate a UPL in addition to the rate setting burden, this change results in a net reduction in burden of 11,904 hours.

Section 438.6(i)(3) Advance directives

1. Requirement

This paragraph requires that MCOs, PIHPs, and certain PAHPs provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

2. Burden

The burden associated with this requirement is the time it takes to furnish the information to enrollees. We assume that this information would be furnished with the rest of the information required by §438.10 and is therefore subsumed under those

requirements.

There is also an implied recordkeeping requirement associated with contracts; i.e., that would be documented. Maintaining documentation is a usual and customary business practice and does not add to the burden.

B. Section 438.8 Provision that apply to PIHPs and PAHPs

1. Requirement

This section specifies which of the contract requirements contained in §438.6 apply to PIHPs and which apply to PAHPs. Requirements for advance directives apply only to PIHPs and certain limited numbers of PAHPs.

2. Burden

PHPs (now designated as PIHPs and PAHPs) have not previously been required to maintain written policies and procedures with respect to advance directives. This rule requires the PIHP and some PAHPs to provide written information to enrollees of their rights under this provision and the PIHPs policies with respect to the implementation of those rights. We project 8 hours of time for each of 123 PIHPs and 2 PAHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 6.3 million individuals enrolled in PIHPs and the specified PAHPs. The total time for this is approximately 212,000 hours.

1. Requirement

Under the physician incentive plan provision, PIHPs and PAHPs, like MCOs, will be required to provide descriptive information to States and CMS to determine whether or not there is substantial financial risk in their subcontracts. In addition, enrollees must be surveyed and provided information on the risk arrangements when substantial risk

exists.

2. Burden

We are basing our projections of burden upon information published in the Federal Register on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than 1/3 of the approximately 157 PIHPs and PAHPs use incentive or risk payment arrangements with their subcontracting providers. Affected PIHPs and PAHPs would be required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. At the projected 100 hours per response for approximately 53 PIHPs and PAHPs the total burden would be 5,300 hours. For those PIHPs and PAHPs with substantial financial risk, there are other requirements such as stop/loss insurance and beneficiary surveys. We believe there would be minimal additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than ¼ of those PIHPs and PAHPs with risk or incentive payments, or a total of 13. We estimate an additional 10 hours per plan for a total of 130 hours. Altogether, we estimate 5,430 hours of burden through imposition of this requirement on PIHPs and PAHPs.

C. Section 438.10 Information requirements

Section 438.10(c), (d), (e), (f), (g), and (h)

1. Requirement

In summary, §438.10 requires that each State, its contracted representative, or at the option of the State, each MCO, PIHP, PAHP, and PCCM furnish information to enrollees and potential enrollees to meet the requirements of this section. Paragraph (c)(4) requires

that the State and each MCO, PIHP, PAHP, and PCCM, make oral interpretation available in languages other than English. Paragraph (c)(5) requires that beneficiaries be informed how to access those services. Paragraph (d)(2) requires that all enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats. The basic information listed in paragraph (e)(2) must be provided to each potential enrollee by the State or its contracted representative.

The State, its contracted representative or the MCO, PIHP, PAHP, or PCCM must provide the information in paragraph (f)(6), and for MCOs and PIHPs, in paragraph (g) at least once a year. The information that must be provided includes the following:

(a) Information for potential enrollees:

(1) General information must be provided about the basic features of managed care, which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PIHP, and MCO and PIHP responsibilities for coordination of enrollee care.

(2) Information specific to each MCO, PIHP, PAHP, and PCCM serving an area that encompasses the potential enrollee's service area must be provided in summary form, or in more detail, upon request of the enrollee. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum, information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients; and benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

(b) Information for enrollees:

(1) The State must notify enrollees of their disenrollment rights annually. The State, or the MCO, PIHP, PAHP, and PCCM, if delegated this responsibility by the State, must provide certain information to new enrollees and notify enrollees annually of their right to request additional information. The State must give each enrollee written notice of any change (that the State defines as "significant") in the information specified at least 30 days before the intended effective date of the change and make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(c) General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs:

(1) Names, locations, and telephone numbers of, and non-English languages spoken by, current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

(2) Any restrictions on the enrollee's freedom of choice among network providers.

(3) Enrollee rights and responsibilities as specified in §438.100.

(4) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in §438.10(g)(i).

(5) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

(6) Procedures for obtaining benefits, including authorization requirements.

(7) The extent to which, and how, enrollees may obtain benefits, including family planning services from out-of-town network providers.

(8) The extent to which, and how, after-hours and emergency coverage are

provided.

(9) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in §438.114, and the fact that prior authorization is not required for emergency services.

(10) The post-stabilization care services rules set forth at §438.113(c) of this chapter.

(11) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(12) Cost sharing, if any.

(13) How and where to access any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

(14) For a counseling or referral service the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, or PCCM need not furnish information on how and where to obtain the service. The State must furnish information about how and where to obtain the service.

(d) Specific information requirements for enrollees of MCOs and PIHPs:

(1) In addition to the requirements in §438.10(e), MCOs and PIHPs must provide to their enrollees the following information specified in §438.10(g):

(i) Grievance, appeal, and fair hearing procedures and timeframes, as provided in §438.400 through 438.424, in a State-developed or State-approved description, which includes:

(ii) The right to a State fair hearing and the method for obtaining a hearing,

(iii) The rules governing representation at the hearing,

(iv) The right to file grievances and appeals

(v) The filing requirements, timeframes, and availability of assistance with the filing process,

(vi) The toll-free numbers enrollees can use to file a grievance or appeal by phone,

(vii) The fact that when requested by the enrollee, benefits will continue if the enrollee files an appeal or a request for a State fair hearing within the specified timeframes,

(viii) The possibility that the enrollee may be required to pay the cost of services furnished during the appeal process, if the final decision is adverse,

(ix) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service,

(x) Information on advance directives, as set forth in §438.6(i)(2) and physician incentive plans, as set forth in §438.6(h) and

(xi) Additional information that is available upon request, including structure and operation of the MCO or PIHP

2. Burden

We believe the burden placed on States, MCOs, PIHPs, PAHPs, and PCCMs, and enrollment brokers as a result of these requirements is the time associated with modifying the content of existing information materials, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it will initially take 12 hours for each MCO, PIHP, PAHP, or PCCM system to modify existing information materials to conform to the requirements above. We further estimate that there are approximately 533 MCOs, PIHPs, PAHPs, and PCCM systems equating to an initial modification burden of approximately 6,396 hours. After the initial modification,

we estimate that it will take MCOs, PIHPs, and PAHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,132 hours.

We estimate that that it will take MCOs, PIHPs, PAHPs, and PCCM systems approximately 5 minutes per enrollee to mail a packet of materials to potential enrollees and enrollees. We estimate that each year approximately 15 percent of the Medicaid managed care enrollee population are new enrollees. This equates to approximately 3.9 million potential enrollees a year for a total burden on the States of 65,000 hours. Mailing the annual packet of information to the 25,731,040 enrollees, at 5 minutes a packet, will result in a burden to the State, or the MCOs, PIHPs, PAHPs, and PCCMs, if delegated this responsibility by the State, of 2,144,253 hours.

We similarly estimate that it annually will take MCOs, PIHPs, PAHPs, and PCCMs 5 minutes per enrollee to supply information requested by potential enrollees and enrollees. We estimate that 10 percent of potential enrollees and enrollees will request information each year. For the 390,000 potential enrollees requesting information, this results in a burden on States of 6,500 hours. For the 2,573,104 enrollees requesting information, this results in a burden on States, or MCOs, PIHPs, PAHPs, and PCCMs if delegated this responsibility by the State, of 214,425 hours.

Section 438.10(i), Special rules: States with mandatory enrollment under State plan authority

1. Requirement

Under (h), if the State plan provides for mandatory MCO or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees. The

information must include the MCO's or PCCM's service area, the benefits covered under the contract, any cost sharing imposed by the MCOs or PCCMs and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

2. Burden

For the requirement to provide information in a chart-like format, we believe that the additional burden on States (i.e., not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take States approximately 8 hours each to create the comparative chart. Currently, 10 States per year have approved managed care under the State Plan Option, for a total annual burden of approximately 80 hours.

D. Section 438.12 Provider discrimination prohibited

1. Requirement

This section requires that if an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

2. Burden

The burden associated with this requirement is the time it takes the MCO, PIHP, or PAHP to draft and furnish the providers with the requisite notice. We estimate that it will take 1 hour to draft and furnish any given notice. We estimate that on average each MCO, PIHP, and PAHP will need to produce 10 notices per year for a total of 4,960 hours.

E. Section 438.50(b) State plan information

1. Requirements

Each State must have a process for the design and initial implementation of the

State plan that involves the public and must have methods in place to ensure ongoing public involvement once the State plan has been implemented.

2. Burden

The burden associated with this section includes the time associated with developing the process for public involvement, including annual updates. We estimate that it will take 10 current States 40 hours per State to develop the process for involving the public for a total burden of 400 hours. We estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 200 hours.

The recordkeeping burden involved in maintaining documentation that the requirements are met is a usual and customary business practice and imposes no additional burden.

F. Section 438.56 Disenrollment: Requirements and limitations

Section 438.56(d)(1)

1. Requirement

In order to disenroll, the beneficiary (or his or her representative) must submit an oral or written request to the State agency (or its agent) or to the MCO, PIHP, PAHP, or PCCM where permitted.

2. Burden

We believe that the burden associated with this requirement is the length of time it would take enrollees to submit in writing a disenrollment request, if they choose to use the written format. We estimate that it will take approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PIHP, PAHP, and PCCM enrollees will request that they be disenrolled from an

MCO, PIHP, PAHP, or PCCM. Approximately one-fourth of the enrollees will choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 321,638 affected enrollees (one-fourth of the 1,286,552 enrollees requesting disenrollment), or approximately 53,606 hours. We estimate a burden of 3 minutes per oral request for disenrollment (for 3/4ths of the 1,286,552 enrollees, or 964,914 enrollees) for a total burden of 48,246 hours.

Section 438.56(f)

1. Requirement

Under paragraph (f), a State that restricts disenrollment under this section must provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

2. Burden

The burden for this section is addressed in §438.10(f).

G. Section 438.102 Enrollee-provider communications

1. Requirement

Section 438.102(a)(2) states that the general rule in paragraph (a)(1) of this section does not require the MCOs, PIHPs, and PAHPs to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds; and makes written information on these policies available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to an any particular service.

2. Burden

We believe the burden associated with this requirement will affect no more than 3

MCOs or PIHPs annually since it applies only to the services they discontinue providing on moral or religious grounds during the contract period. We estimate that it takes 4 hours to devise a notice and 5 minutes to mail, affecting 52,000 enrollees, for a total burden of 4,345 hours. [12 hours + (52,000 x 1/12)] The burden for notification of prospective enrollees of the services not covered by the MCO, PIHP, or PAHP on these grounds is included in the overall burden arising from the Information Requirements in §438.10.

H. Section 438.202 State responsibilities

1. Requirement

Each State contracting with an MCO or PIHP must have a written strategy for assessing and improving the quality of managed care services offered by the MCO or PIHP, make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy. We expect States will conduct these periodic reviews every 3 years. Each State must also submit to CMS a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, States are required to submit to CMS regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness.

2. Burden

The burden associated with this section is limited to those States offering managed care through MCOs or PIHPs (41) and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments**,** submitting an initial copy of the strategy to CMS prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy. We estimate that it will take 40 hours per State to develop the

proposed strategy for a total burden of 1,640 hours. We estimate that publicizing the proposed strategy will take 2 hours per State for a total burden of 82 hours. We estimate that incorporating public comments for the final strategy will take another 40 hours per State for a total burden of 1640 hours. We estimate it will take 1 hour per State to submit an initial copy of the strategy to CMS prior to implementation and whenever significant changes are made for a total of 41 hours. We estimate it will take 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy and that these reports will be submitted at approximately every 3 years for a total annual burden of 546 hours.

I. Section 438.204 Elements of State Quality Strategies:

1. Requirement

In the final rule we require at §438.204(b)(2) that a State identify the race, ethnicity, and primary language spoken by each MCO and PIHP enrollee and report this information to each MCO and PIHP in which each beneficiary enrolls at the time of their enrollment.

2. Burden

We believe that most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this would require 4 hours of programming for each of the 41 jurisdictions for a total of 164 hours.

J. Section 438.207 Assurances of Adequate Capacity and Services

1. Requirement

Section 438.207(b) requires that each MCO, PIHP, and PAHP (where applicable)

submit documentation to the State, in a format specified by the State, to demonstrate that it has the capacity to demonstrate that it complies with specified requirements and that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care and meets specified requirements.

Section 438.207(c) requires that this documentation be submitted to the State at the time the MCO, PIHP, or PAHP enters into a contract with the State and at any time there has been a significant change (as defined both by the State and this regulation) in the MCO's, PIHP's, or PAHPs operations that would affect adequate capacity and services.

Section 438.207(d) requires the State, after reviewing the MCO's, PIHP's, or PAHP's documentation, to certify to CMS that the MCO, PIHP, or PAHP has complied with the State's requirements for availability of services, as set forth at §438.206.

2. Burden

We believe that MCOs, PIHPs, and PAHPs already collect and provide this information to State agencies as part of their customary and usual business practices and that the only additional burden on MCOs, PIHPs, and PAHPs is the length of time required for these entities to compile this information in the format specified by the State agency, and the length of time to mail the information to the State and to CMS. We estimate that it will take each MCO, PIHP, and PAHP approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 486 MCOs, PIHPs, and PAHPs with networks, or approximately 9,720 hours. In addition, we estimate that it will take MCOs, PIHPs, and PAHPs approximately 5 minutes each to mail the materials associated with this burden to the State for an annual burden of approximately 5 minutes multiplied by 486 of these entities, or approximately 4 hours.

We estimate that obtaining information on: (1) the numbers and types of persons

with special health care needs that could be anticipated to enroll in the MCO or PIHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PIHPs network; and (4) the numbers and types of additional experienced providers needed, would require an estimated 40 hours of work for each of the 462 MCOs, PIHP, and PAHP for a total estimated burden of 18,480 hours.

K. Section 438.208 Coordination and continuity of care

1. Requirement

Under paragraph (b)(3) of this section requires MCOs, PIHPs, and PAHPs to share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities need not be duplicated.

2. Burden

The burden associated with this information collection requirement is the time it will take to disclose information on enrollees. We estimated that it will be necessary to disclose information on 619,709 enrollees and take it will take 45 minutes for each one, for an annual total of 464,782 hours.

L. Section 438.210 Coverage and authorization of services

1. Requirement

Under paragraph (b) of this section, for the processing of requests for initial and continuing authorizations of services, each contract must require that the MCO, PIHP, or PAHP and its subcontractors have in place written policies and procedures.

2. Burden

The burden associated with this requirement is the time required to develop the policies and procedures. We do not believe that this requirement will increase an entity's

burden as it part of usual and customary business practices.

1. Requirement

Under paragraph (c) of this section, each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested.

2. Burden

The burden associated with this requirement will be the time required to notify the requesting provider and the enrollee. We believe that there will be approximately 100 notifications under this provision and that it will take 60 minutes to complete the notification (including writing it) per MCO or PIHP. There are approximately 339 MCOs and 123 PIHPs for a total of 462 for a total of 46,200.

M. Section 438.214 Provider selection

1. Requirement

Under this section, each State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers.

2. Burden

The burden associated with this requirement is the usual and customary recordkeeping collection associated with maintaining documentation.

N. Section 438.230 Subcontractual relationships and delegation

1. Requirement

Under paragraph (b), there must be a written agreement that specifies the activities and report responsibilities delegated to the subcontractor and provides for revoking

delegation or imposing other sanctions if the subcontractor's performance is inadequate.

2. Burden

The burden associated with this requirement is the time required to write the agreement and the time required to maintain documentation of the agreement. We believe that these activities and usual and customary business practices and do not affect the entities' burden.

O. Section 438.236 Practice guidelines

1. Requirement

Under paragraph (c) of this section, each MCO, PIHP, and PHAP must disseminate guidelines to its affected providers and, upon request, to enrollees and potential enrollees.

2. Burden

The burden associated with this requirement is the time required to disseminate the guidelines. We believe that these will be rare requests and will occur infrequently.

P. Section 438.240 Quality assessment and performance improvement program; Performance improvement projects

1. Requirement

Section 438.240(c) states that each MCO and PIHP must annually measure its performance using standard measures required by the State and report its performance to the State. In addition to using and reporting on measures of its performance, §438.240(d)(1) requires States to ensure that each MCO and PIHP have an ongoing program of performance improvement projects. In §438.240(d)(2) each MCO and PIHP is required to report the status and results of each such project to the State as requested.

2. Burden

This regulation requires States to require each MCO and PIHP to have an ongoing

program of performance improvement. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. Because the use of performance measures in managed care has become commonplace in commercial, Medicare, and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or States.

With respect to the requirements for ongoing performance improvement projects in §438.240(d), we expect that, in any given year, each MCO and PIHP will complete two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PIHP's projects annually. Accordingly, we estimate that it will take each MCO and PIHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PIHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 462 MCOs and PIHPs, or approximately 13,860 hours.

Q. Section 438.242 Health information systems

1. Requirement

Section 438.242(b)(1) requires the State to require each MCO and PIHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Paragraph (3) requires that the data be made available to the State and, upon request, to CMS.

2. Burden

The above information collection requirement is subject to the PRA. However, we believe that the burden associated with these information collection requirements is exempt from the Act in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial

resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

R. Section 438.402 General requirements

1. Requirement

In summary, §438.402 requires each MCO and PIHP to have a grievance system, sets out general requirements for the system, and establishes filing requirements. It provides that grievances and appeals may be filed either orally or in writing, but that oral appeals (except those with respect to expedited service authorization decisions) must be followed by a written request.

2. Burden

We estimate that it will take approximately 5.5 hours for each MCO and PIHP to conform their existing general grievance system requirements to those in the regulation. It will take approximately 2.5 hours to create or change the filing requirements, including developing or revising templates for a notice of action and a notice of disposition or resolution. The total burden for 462 MCOs and PIHPs is 3,696 hours.

We estimate that approximately 1 percent of 23.7 million MCO and PIHP enrollees (237,000) annually will file a grievance with their MCO or PIHP and that approximately .5 percent (118,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 118,500 hours.

S. Section 438.404 Notice of action

1. Requirement

In summary, §438.404 states that if an MCO or PIHP intends to deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with

one MCO or PIHP to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner, the MCO or PIHP must give the enrollee timely written notice and sets forth the requirements of that notice.

2. Burden

We estimate that the burden associated with this requirement is the length of time it would take an MCO or PIHP to provide written notice of an intended action. We estimate that it will take MCOs and PIHP 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,185,000) of the approximately 23.7 million MCO and PIHP enrollees will receive one notice of intended action per year from their MCO or PIHP for a total burden of approximately 9,875 hours.

T. Section 438.406 Handling of grievances and appeals

1. Requirement

In summary, §438.406 states that each MCO and PIHP must acknowledge receipt of each grievance and appeal.

2. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

U. Section 438.408 Resolution and notification: grievances and appeals

1. Requirement

In summary, §438.408 states that for grievances filed in writing or related to quality of care, the MCO or PIHP must notify the enrollee in writing of its decision within specified timeframes. The notice must also specify that the enrollee has the right to seek further review by the State and how to seek it. All decisions on appeals must be sent to the enrollee in writing within specified timeframes and for notice of expedited resolution, the

MCO or PIHP must also provide oral notice. The decision notice must include the MCO or PIHP contact for the appeal and the results of the process and the date it was completed. For an oral grievance that does not relate to quality of care, the MCO or PIHP may provide oral notice unless the enrollee request that it be written.

2. Burden

The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

V. Section 438.410 Expedited resolution of appeals

1. Requirement

Paragraph (c), Action following denial of a request for expedited resolution, requires each MCO and PIHP to provide written notice to an enrollee whose request for expedited resolution is denied.

2. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

W. Section 438.414 Information about the grievance system to providers and subcontractors.

1. Requirement

Under this section, the MCO or PIHP must provide the information specified at §438.10(g)(i) about the grievance system to all providers and subcontractors at the time they enter into a contract.

2. Burden

The burden associated with this requirement is the time required to include the necessary language in the contract. We believe that this is usual and customary business

practice and does not add any burden.

X. Section 438.416 Record keeping and reporting requirements

1. Requirement

This section requires the State to require MCOs and PIHPs to maintain records of grievances and appeals.

2. Burden

We estimate that approximately 95,000 (.5 percent) of the approximately 19 million MCO and PIHP enrollees will file a grievance or appeal with their MCO or PIHP (205 per MCO or PIHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (3.4 hours per MCO or PIHP), for a total burden of 1,583 hours (1 minute multiplied by an estimated 95,000 enrollees who would file a grievance or appeal).

Y. Section 438.604 Data that must be certified

1. Requirement

The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

2. Burden

While the requirement for MCOs and PIHPs is to certify all documents required by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, we are assigning 1 token hour of burden for this requirement

Z. Section 438.608 Program integrity requirements.

1. Requirement

Under this section, the MCO or PIHP must have administrative and management arrangements or procedures that are designed to guard against fraud and abuse. The arrangements or procedures must include written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards and the designation of a compliance officer and a compliance committee that are accountable to senior management.

2.Burden

The burden associated with this requirement is the time required to file a copy of the written procedures. We believe that this is a normal business practice and does not add any burden.

AA. Section 438.710 Due process: Notice of sanction and pre-termination hearing

Section 438.710(a) Due process: notice of sanction and pre-termination hearing

1. Requirement

Section 438.710(a) states that before imposing any of the sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction.

2. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.710 (b)(2) Due process: notice of sanction and pre-termination hearing

1. Requirement

Section 438.710(b)(2) states that before terminating an MCO's or PCCM's contract, the State must:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for

termination, the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with §438.10, on their options for receiving Medicaid services following the effective date of termination.

2. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

BB. Section 438.722 Disenrollment during termination hearing process

1. Requirement

Section 438.722(a) states that after a State has notified an MCO or PCCM of its intention to terminate the MCO's or PCCM's contract, the State may give the MCO's or PCCM's enrollees written notice of the State's intent to terminate the MCO's or PCCM's contract.

2. Burden

States already have the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that 12 States may terminate 1 contract per year. We estimate that it will take States 1 hour to prepare the notice to enrollees, for a total burden of 12 hours. In addition, we estimate that it will take States approximately 5 minutes per

beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States multiplied by 46,194 beneficiaries per MCO or PCCM, for a burden of approximately 46,194 hours. The total burden of preparing the notice and notifying enrollees is 46,206.

CC. Section 438.724 Notice to CMS

1. Requirement

Section 438.724 requires that the State give the CMS Regional Office written notice whenever it imposes or lifts a sanction. The notice must specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

2. Burden

We anticipate that no more than 36 States would impose or lift a sanction each year and that it would take each one 30 minutes to give the regional office notice. Thus the annual burden would be 18 hours.

DD. Section 438.730 Sanction by CMS: Special rules for MCOs with risk contracts

1. Requirement

Section 438.730(b), Notice of Sanction, requires that if CMS accepts a State agency's recommendation for a sanction, the State agency gives the MCO written notice of the proposed sanction.

Paragraph (c) of this section, Informal reconsideration, requires that if the MCO submits a timely response to the notice of sanction, the State agency gives the MCO a concise written decision setting forth the factual and legal basis for the decision. In addition, if CMS reverses the State's decision, the State sends a copy to the MCO.

2. Burden

These requirements are exempt under 5 CFR 1320.4(a) because they occur as part

of administrative actions.

EE. Section 438.810 Expenditures for Enrollment Broker Services:

1. Requirement

Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to CMS for review and approval.

2. Burden

The burden associated with this requirement is the length of time for a State to mail each contract to CMS for review. We estimated that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 3 hours per year (5 minutes multiplied by an estimated 35 enrollment broker contracts in the States using brokers).

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above in §§438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.202, 438.204, 438.207, 438.208, 438.210, 438.214, 438.230, 438.236, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.608, 438.710, 438.722, 438.724, 438.730, and 438.804. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services

Office of Information Services,

DCES, SSG

Attn: Julie Brown, CMS-2104-F

Room N2-14-26

7500 Security Boulevard, Baltimore, MD 21244-1850;

and

Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503

Attn: Brenda Aguilar, Desk Officer.